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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,917	03/30/2004	Yasuyuki Numajiri	00684.003620.	3182
5514	7590	07/17/2006	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO			TURK, NEIL N	
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1743

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/811,917	Applicant(s) NUMAJIRI, YASUYUKI	
	Examiner Neil Turk	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) 7-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date <u>8/27/04, 1/21/05, 5/6/04</u></p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: ____.</p> |
|---|---|

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to a biochemical reaction cartridge, classified in class 422, subclass 33.
 - II. Claims 7-10, drawn to a biochemical treatment apparatus, classified in class 73, subclass 863.03.
 - III. Claims 11-15, drawn to a biochemical treatment process, classified in class 436, subclass 43.
 - IV. Claims 16-19, drawn to a biochemical reaction cartridge, classified in class 422, subclass 236.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require an injection port as needed in the subcombination. The subcombination has separate utility such as being useable alone, on a desktop per se and operated by a user, not requiring a cartridge mounting portion.

Inventions I, II, and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of I as claimed can be used to practice another and materially different process such as one utilizing positive pressure, hydrostatic pressure, or other means for flowing the solution. The process as claimed in III can be practiced by another materially different apparatus, such as one that does not require a cartridge mounting portion or control means for controlling fluid pressure.

Inventions I, II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not capable of use together and have different modes of operation, and effects. Invention I requires only a first and second chamber and passage for the specimen/reagent/reaction liquid, and invention II requires a storage chamber, first chamber, and second chamber, with connecting passages in certain height orientation relative to one another. Additionally, invention I has the effect of a biochemical reaction through induction of a specimen and a reagent, whereas invention II does not have this effect with only a liquid accumulated in the storage chamber. Invention IV has a design with a storage chamber, first chamber, and second chamber

with special passageways fluidly connecting the chambers, whereas invention II requires a cartridge mounting portion and control means for controlling fluid pressure.

Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus of invention IV as claimed can be used to practice another and materially different process such as one that does not require nozzle ports and injecting fluid into the cartridge.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Jason Okun on July 3rd, 2006 a provisional election was made with traverse to prosecute the invention of I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention,

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. JP 2003-094241, filed on March 31, 2003 and JP 2003-097136, filed on March 31, 2003.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Full translations of JP 2003-094241 and JP 2003-097136 must be filed in order for claimed foreign priority under 35 USC 119 to be attained.

Claim Objections

4. **Claim 5** is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 recites the limitation of "said particles of a magnetic material", and there is no antecedent basis for such a limitation established in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 5** recites the limitation "said particles" in line 2 of claim 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-6** are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding (5,928,880). Wilding shows in figure 5 a representation of the combination of the sample preparation device of fig. 1 and the analytical device 110 designed to carry out various binding assay protocols, and polynucleotide amplification (lines 21-24, col. 10, fig. 5). Wilding shows in figure 5 several injection ports (nozzle ports, included on both sides of the cartridge in a mirrored fashion) and chambers for passing a reagent to be reacted with an analyte, which flow through fluidly connected flow paths and reaction chambers that is constructed to a substantially rectangular parallelepiped structure (lines 21-67, col. 10, fig. 5). Wilding also discloses a wash chamber 135, washing the immobilized reagent and expelling any unbound reagents that may be routed to a waste receptacle within the device (lines 7-11, col. 14; lines 31-39, col. 19). Wilding also discloses that the outlet of flow path 12a, 12b is in fluid communication with the inlet port 114 (injection port) and the discharge section 28 of channel 24a, 24b is in fluid communication with inlet port 124 (lines 25-35, col. 10) and Wilding discloses that reagents may be supplied through ports 116 /126 and a reaction region 117/127 is provided in the assay structure 112/122 in which a suitable reagent interacts with the analyte (first and second chamber with analyte/reagent and a passage between for the reagent/analyte for a biochemical reaction) to yield a detectable product (lines 35-39, col. 10, fig. 5). Wilding further discloses that the system is advantageously combined with an appliance that serves to deliver fluid to, discharge fluid from, and transfer fluid

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between the respective devices, and the appliance has a nesting site 52 for registering ports in the devices with flow lines in the appliance (the appliance connects to the ports to apply or reduce pressure) (lines 14-30, col. 11, figs. 6a, 6b, and 7). Wilding further discloses that the appliance typically includes an impellent; such as pump 58 for forcing fluid through the analytical system (lines 27-28, col. 11). Wilding further discloses that the analytical device may include an appliance, like that of appliance 90 of fig. 7, which includes flow path paths mated to ports 216a, 216b, 216c, and 216d in the device 210 (lines 38-43, col. 20, fig. 11b). Wilding discloses that the appliance may also include valves (nozzles) that allow the ports 216a, 216b, 216c, and 216d to be mechanically opened and closed (applying or reducing pressure). Wilding also discloses that the valves in the appliance, or alternatively, in the devices themselves, may be utilized to direct fluid flow (lines 47-51, col. 20). With regard claim 5, Wilding discloses that a mass of magnetic particles may be retained in a relatively fixed position in flow path 12a, 12b by means of an applied magnetic field to effect filtration of particulate matter from the test sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8919. The examiner can normally be reached on Mon-Fri 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT



**YELENA GAKH
PRIMARY EXAMINER**